

Annex V EC Declaration of Conformity

Manufacturer Name and Address:	Kerr Corporation 1717 W. Collins Ave., Orange, CA 92867, USA
Authorized Representative Name and Address:	Kerr Italia S.r.l. Via Passanti, 174 Scafati (SA) 84018, Italy
Technical File Name/Number:	Premise Technical File, R095
Product Tradename(s):	Premise
Device Identification:	See Attachment 1
Classification and Rule(s):	Ila per Annex IX, Rule 8
Notified Body:	BSI Group The Netherlands B.V.
Notified Body Number:	2797
Conformity Assessment Procedure & Certificate Issued:	Annex V – Production Quality Assurance CE Certificate Number 00847

Declaration Statement:

We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

15 October 2021

Issue date



Name: Mark Dzendzel

Title: Director, Quality Assurance Systems

**Premise – Attachment 1
to Annex V EC Declaration of Conformity**

REF	Description
32712	Premise Refill Syringe Enamel A1
32713	Premise Refill Syringe Enamel A2
32714	Premise Refill Syringe Enamel A3
32715	Premise Refill Syringe Enamel A3.5
32716	Premise Refill Syringe Enamel A4
32717	Premise Refill Syringe Enamel B1
32718	Premise Refill Syringe Enamel B2
32719	Premise Refill Syringe Enamel B3
32720	Premise Refill Syringe Enamel B4
32721	Premise Refill Syringe Enamel C1
32722	Premise Refill Syringe Enamel C2
32723	Premise Refill Syringe Enamel C3
32724	Premise Refill Syringe Enamel C4
32725	Premise Refill Syringe Enamel D2
32726	Premise Refill Syringe Enamel D3
32727	Premise Refill Syringe Enamel D4
32728	Premise Refill Syringe Enamel XL1
32729	Premise Refill Syringe Enamel XL2
32730	Premise Refill Syringe Dentine A2
32731	Premise Refill Syringe Dentine A3
32732	Premise Refill Syringe Dentine A3.5
32733	Premise Refill Syringe Dentine A4
32734	Premise Refill Syringe Dentine B1
32735	Premise Refill Syringe Dentine B2
32736	Premise Refill Syringe Dentine C2
32737	Premise Refill Syringe Dentine D2
32738	Premise Refill Syringe Translucent Amber
32739	Premise Refill Syringe Translucent Grey
32740	Premise Refill Syringe Translucent Clear
32741	Premise Refill Syringe Translucent Super Clear
32745	Premise Refill Unidose Enamel A1
32746	Premise Refill Unidose Enamel A2
32747	Premise Refill Unidose Enamel A3
32748	Premise Refill Unidose Enamel A3.5
32749	Premise Refill Unidose Enamel A4
32750	Premise Refill Unidose Enamel B1
32751	Premise Refill Unidose Enamel B2
32752	Premise Refill Unidose Enamel B3
32753	Premise Refill Unidose Enamel B4
32754	Premise Refill Unidose Enamel C1
32755	Premise Refill Unidose Enamel C2

REF	Description
32756	Premise Refill Unidose Enamel C3
32757	Premise Refill Unidose Enamel C4
32758	Premise Refill Unidose Enamel D2
32759	Premise Refill Unidose Enamel D3
32760	Premise Refill Unidose Enamel D4
32761	Premise Refill Unidose Enamel XL1
32762	Premise Refill Unidose Enamel XL2
32763	Premise Refill Unidose Dentine A2
32764	Premise Refill Unidose Dentine A3
32765	Premise Refill Unidose Dentine A3.5
32766	Premise Refill Unidose Dentine A4
32767	Premise Refill Unidose Dentine B1
32768	Premise Refill Unidose Dentine B2
32769 E	Premise Refill Unidose Dentine C2
32770	Premise Refill Unidose Dentine D2
32771	Premise Refill Unidose Translucent Amber
32772	Premise Refill Unidose Translucent Grey
32773	Premise Refill Unidose Translucent Clear
32774	Premise Refill Unidose Translucent Super Clear
35372	Premise Syringe Mini Kit